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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,164	12/20/2001		Benjamin J. Metcalf	33,484-00	3977
25291	7590	06/24/2003			
WYETH			EXAMINER		
PATENT LAW GROUP FIVE GIRALDA FARMS				DUFFY, PATRICIA ANN	
MADISON, N	J 07940			ART UNIT	PAPER NUMBER
				1645	
				DATE MAILED: 06/24/2003	0

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 10/109,164

Applicant(s)

Metcalf

Examiner

Patricia A. Duffy

Art Unit **1645** 



The MAILING DATE of this communication appears on	the cover sheet with the correspondence address
Period for Reply	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO THE MAILING DATE OF THIS COMMUNICATION.	D EXPIRE <u>one</u> MONTH(S) FROM
· Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no	event, however, may a reply be timely filed after SIX (6) MONTHS from the
mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a reply within the s	tatutory minimum of thirty (30) days will be considered timely.
<ul> <li>If NO period for reply is specified above, the maximum statutory period will apply and</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the a</li> </ul>	•
- Any reply received by the Office later than three months after the mailing date of this	
earned patent term adjustment. See 37 CFR 1.704(b).  Status	
1) Responsive to communication(s) filed on	·
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This action	n is non-final.
3) Since this application is in condition for allowance exclosed in accordance with the practice under Ex parts	cept for formal matters, prosecution as to the merits is Quayle, 1935 C.D. 11; 453 O.G. 213.
Disposition of Claims	•
4) 💢 Claim(s) <u>1-17</u>	is/are pending in the application.
	is/are withdrawn from consideration.
5) Claim(s)	is/are allowed.
6) Claim(s)	is/are rejected.
7)	is/are objected to.
8) 💢 Claims 1-17	are subject to restriction and/or election requirement.
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/are a	☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the dra-	wing(s) be held in abeyance. See 37 CFR 1.85(a).
11) The proposed drawing correction filed on	is: a) $\square$ approved b) $\square$ disapproved by the Examiner.
If approved, corrected drawings are required in reply to	
12) The oath or declaration is objected to by the Examine	r.
Priority under 35 U.S.C. §§ 119 and 120	
13) $\square$ Acknowledgement is made of a claim for foreign prior	rity under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:	·
1. $\square$ Certified copies of the priority documents have	been received.
2. $\square$ Certified copies of the priority documents have	been received in Application No
3. Copies of the certified copies of the priority doc application from the International Bureau	uments have been received in this National Stage (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the	certified copies not received.
14) Acknowledgement is made of a claim for domestic production of the companion of the comp	iority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional a	
15) ☐ Acknowledgement is made of a claim for domestic pr	iority under 35 U.S.C. §§ 120 and/or 121.
Attachment(s)	
1) Notice of References Cited (PTO-892) 4	Interview Summary (PTO-413) Paper No(s).
	Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	Other:

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## DETAILED ACTION

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, drawn to the first technical feature of a plasmid comprising a tightly regulated promoter operatively linked to a nucleic acid that encodes a peptidoglycan-associated lipoprotein of gram negative bacteria.

Group 2, claim(s) 9-10, drawn to the first method of use of the first technical feature comprising producing a recombinant lipidated peptidoglycan-associated lipoprotein.

Group 3, claim(s) 11-15, drawn to the second technical feature of an antigenic composition comprising a recombinant lipidated peptidoglycan-associated lipoprotein.

Group 4, claim(s) 16-17, drawn to a first method of use of the second technical feature, that is immunizing against a gram-negative bacterium.

2. The inventions listed as Groups 1-4 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

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corresponding special technical features for the following reasons: The technical feature of Group 1 is a plasmid comprising a tightly regulated promoter operatively linked to a nucleic acid that encodes a peptidoglycan-associated lipoprotein of gram negative bacteria. The technical feature of Groups 3 and 4 are a recombinant protein and as such lack the technical feature of Group 1. Further, the technical feature of Group 1 is anticipated by either of WO 90 02557 (of record in international examination) that teaches a plasmid containing the lac promoter (i.e. a tightly regulated promoter) operatively linked to an isolate nucleic acid encoding the PBOMP-1 protein, which is another name for the P6 protein of the claimed invention. As such, this first appearing technical feature is not "special" within the meaning of PCT Rule 13.2 because it fails to provide a novel contribution over the prior art. Consequently, the inventions of Groups 2-4 lack unity of invention with Group 1.

- 3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 4. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

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applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D. June 13, 2003

> Patricia A. Buffy, Ph.D. Primary Examiner Group 1600